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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,481	03/05/2001	Frank Hulstaert	11362.0034.P	8708
7590 12/14/2004				
Patricia A Kammerer Howrey Simon Arnold & White 750 Bering Drive Houston, TX 77057-2198			EXAMINER NICHOLS, CHRISTOPHER J	
			ART UNIT 1647	PAPER NUMBER

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/786,481

Applicant(s)

HULSTAERT ET AL.

Examiner

Christopher J Nichols, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5,8,11 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,8,11 and 18-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,5,8,11 and 18-20 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of Application, Amendments, and/or Claims*

1. **The Finality of the Rejection mailed 2 September 2003 is hereby withdrawn to allow entry of new rejections based on a new reference. Prosecution on the merits is hereby reopened.**
2. The Request for Correction of Inventorship under 37 C.F.R. 1.48(a) filed 14 October 2004 has been received and entered. It is hereby GRANTED by the Examiner. The Inventorship of the instant application is now: Frank Hulstaert, Eugene Vanmechelen, Hugo Vanderstichele, André Van de Voorde, and Stefann Van Gool.
3. The Oath/Declaration filed 14 October 2004 has been received and entered in full.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims **1, 5, 8, 11, 18, 19, and 20** are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,797,478 B1 (28 September 2004) Zemlan & Campbell.
5. US '478 teaches a method of measuring the level of tau in cerebrospinal fluid (CSF) to determine the presence and/or severity of central nervous system (CNS injury) including but not limited to cerebral infarct, cerebral hypoxic injury, cerebral vascular accidents, and/or central

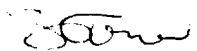
Art Unit: 1647

nervous system tumors thus meeting the limitations of claims 1 and 18 (Col. 3-5). As claimed “anoxia” and “ischemia” fall into the rubric of “cerebral vascular accidents” thus meeting the limitations of claims 1 and 18. US ‘478 also teaches that tau includes any or all of the six non-cleaved isoforms of tau as well as cleaved forms thus meeting the limitations of claims 1 and 18 (Col. 4-5). US ‘478 also teaches calibrating the level of tau in CSF based on patients without axonal degeneration versus patients with axonal degeneration (CNS injury) thus meeting the limitations of claims 1 and 18 (Col. 5).

6. Also the causative agents and/or events of said anoxia and ischemia are also anticipated by US ‘478 which teaches practicing the method for primary hemorrhages including cerebral hemorrhage and arterial occlusion which includes thrombosis thus meeting the limitations of claims 8 and 19 (Col. 3). US ‘478 also teaches practicing the method above to “ascertain or predict clinical outcome following such trauma” thus meeting the limitations of claims 11 and 20 (Col. 3).

*Summary*

7. No claims are allowed.

  
**SHARON L. TURNER, PH.D.**  
**PATENT EXAMINER**  
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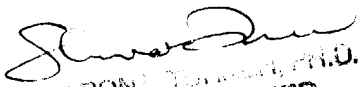
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN  
December 9, 2004

  
SHARON L. NICHOLS, Ph.D.  
PATENT EXAMINER  
12-10-04